UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,307	10/16/2001	Ganapati R. Mauze	10003714	7843

7590 05/27/2005

AGILENT TECHNOLOGIES, INC.
Legal Department, DL429
Intellectual Property Administration
P.O. Box 7599
Loveland, CO 80537-0599

EXAMINER	
FREDMAN, JEFFREY NORMAN	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 05/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/982,307	MAUZE ET AL.	
	Examiner	Art Unit	
	Jeffrey Fredman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *April 7.2005* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-37* is/are pending in the application.

4a) Of the above claim(s) ____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

S.00

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 7, 2005 has been entered.

Claim Interpretation

2. Prior to examination, the claims must be analyzed, since claim construction precedes application of the statutory requirements for patentability.

Applicant has extensively amended claim 21, but the amendment fails to impose any structure on the apparatus. In claim 21, as noted previously, the term "cartridge" or "body fluid analyzing cartridge" carries no weight whatsoever, and anything may be a "cartridge". The language such as "mated with", "for fluid communication with" and "being a modular subcomponent of said associated sensing cartridge" all represent functional limitations in an apparatus. As MPEP 2114 makes clear, "claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function." No specific structure is required or imposed by the term "configured to be inserted into an instrument" other than that a sensor device of some sort can analyze the cartridge in some way.

As noted previously, the first paragraph of claim 21, with the "mated" language, simply requires a component. There is no particular structural elements required by this paragraph whatsoever. The second paragraph requires that the "base element" component have a fluid entry port, the third paragraph requires a "fluid reservoir" that is connected to the port and which is also connected to the sensing element.

The requirement for "fluid communication" between the sensor cartridge and the companion cartridge is a structural element which is met by the currently cited prior art.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 21-23, 26-34 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Lipshutz et al (U.S. Patent 5,856,174).

Lipshutz teaches a "cartridge" (see figure 3 and column 2, lines 15-43) and an analytical instrument (see figure 3) of claim 21 which comprises

A base element that can be "mated with" an analysis device (see column 11, lines 48-52), where Lipshutz expressly teaches that the reaction chamber portion can be "mated with a reusable base unit (see column 26, lines 43-67)" which provides some elements.

Lipshutz further teaches the presence of an entry port (see column 16, lines 15-18, where an inlet port for the entire device is suggested),

A fluid reservoir (see column 26, lines 43-67 and see column 16, lines 18-20, where a "storage chamber" is discussed),

And where these are in fluide communication using a fluid transport system (column 2, line 23),

Where the cartridge performs an operation including a hybridization reaction chamber (see column 2, lines 26-28), or an amplification chamber used for PCR amplification (see column 2, lines 48-53 and column 6, lines 28-67).

As noted previously, Lipshutz teaches that the "cartridge" may be connected to a sensing "cartridge" either directly or indirectly (see column 11, lines 48-52) and is thereby shaped to interact with the remainder of a "diagnostic instrument".

With regard to claim 22, Lipshutz teaches the use of a fluid interface such as capillary electrophoresis for detection (see column 12) as well as by a mechanical/electrical interface into a reader device (column 13, lines 25-35).

With regard to claims 23, Lipshutz teaches a reagent storage system in the cartridge which are connected to fluid channels (see column 16, lines 15-20).

With regard to claims 26-28, 36, Lipshutz teaches thermocycling to perform PCR in fluid communication with a reservoir (see column 6, lines 28-67 and column 16, lines 12-20).

With regard to claims 29, 32, 33, Lipshutz teaches fluid transport systems (see column 2, line 23, for example) (Claims 32 and 33 do not structurally delimit the device since no structural element is included which effects the process step of mixing).

With regard to claim 30, Lipshutz teaches fluid systems which transport fluid to some chambers thereby increasing their volume (see column 2, lines 15-43).

With regard to claim 31, Lipshutz teaches a waste retrieval system (see figures 4A-C, where element 414 is the waste reservoir).

With regard to claim 34, Lipshutz teaches a device in which a sensor device and a companion cartridge are integrated on a single device in fluid communication with one another (see figure 3, for example).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 24, 25, 35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al (U.S. Patent 5,856,174) in view of Leiner et al (U.S. Patent 6,037,178).

Lipshutz teaches the limitations of claims 21-23, 26-34, and 36 as discussed above. Lipshutz does not teach the use of calibration cartridges.

Leiner teaches the use of calibration cartridges (see abstract and column 2).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use a calibration cartridge as taught by Leiner with the device of Lipshutz since Liener states "It is an object of the present invention to propose methods of quality control and quality control liquids which will permit first a control measurement and then measurement of a specimen by means of one and the same single-use cartridge, in addition to providing information on the reliability of the analyzer, or rather, reliability and accuracy of the individual sensors contained in the single-use cartridge (see column 3, lines 45-51)." So an ordinary practitioner would have been motivated to include a calibration cartridge in order to improve the reliability and accuracy of the device. Further, it would have been prima facie obvious to use reservoirs in common for common reagents in order to minimize the number of separate solutions necessary to store in the device.

Response to Arguments

8. Applicant's arguments filed April 7, 2005 have been fully considered but they are not persuasive.

Applicant argues that Lipshutz does not teach a cartridge that is "mated with" an associated sensing cartridge. This is simply not correct. Lipshutz teaches "Following amplification and/or labeling, the nucleic acid sample is incubated with the oligonucleotide array in the hybridization chamber. Hybridization between the sample nucleic acid and the oligonucleotide probes upon the array is then detected, using, e.g., epifluorescence confocal microscopy. Typically, the detection operation will be performed using a reader device external to the diagnostic device. However, it may be desirable in some cases, to incorporate the data gathering operation into the diagnostic device itself." (see column 11, lines 43-52). This is an express teaching of both internal and external "sensing cartridges" which are "mated with" the cartridge of Lipshutz.

Applicant also argues that Lipshutz does not teach "fluid reservoirs". However, Lipshutz expressly teaches "The reaction chamber is also provided with additional elements for transporting a fluid sample to and from the reaction chamber. These elements include one or more fluid channels (122 and 110 in FIGS. 2A and 2B, respectively) which connect the reaction chamber to an inlet/outlet port for the overall device, additional reaction chambers, storage chambers or one or more analytical chambers (see column 16, lines 12-18)." The express teaching of storage chambers is a teaching of fluid reservoirs. The argument with regard to the connection of the fluid reservoir to the "sensing cartridge" does not distinguish Lipshutz, who teaches an internal sensing cartridge which is fluidly connected to the storage chambers. Further, the reaction chamber itself can function as a "reservoir" and it is also fluidly connected

to the sensing cartridge. Therefore, there is no structural difference between the device of Lipshutz and the currently claimed invention.

Applicant expressly argues that Lipshutz does not teach a "dual use" for the fluid reservoir. For prior art to anticipate an apparatus, there is no requirement that the prior art anticipate the use, only that it anticipate the structure claimed. As MPEP 2114 makes clear, "claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function." Here, there is no difference in structure, irrespective of the argued difference in function.

The 103 rejection is maintained since the arguments are similar to those argued towards the 102 rejection over Lipshutz.

Conclusion

9. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey Fredman
Primary Examiner
Art Unit 1637